



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/824,936

04/14/2004

Vahid Saadat

USGINZ00700

7289

40518 7590 05/22/2009
LEVINE BAGADE HAN LLP
2400 GENG ROAD, SUITE 120
PALO ALTO, CA 94303

EXAMINER

KASZTEJNA, MATTHEW JOHN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

05/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,936	Applicant(s) SAADAT ET AL.	
	Examiner MATTHEW J. KASZTEJNA	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,19,23,24,26,27,29-33,36-38,40-43 and 65-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9,19,23,24,26,27,29-33,36-38,40-43 and 65-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2009 has been entered.

Notice of Amendment

In response to the amendment filed on April 15, 2009, amended claims 1, 8, 24, 31 and 36; canceled claims 3-4, 16-18 and 34; and new claims 65-77 are acknowledged. The following new and reiterated grounds of rejection are set forth:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3739

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-7, 23, 26-27, 29, 31-32, 42-43, 65-69 and 74-76 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-6, 13-18, 22-23, 31, 32-36 and 42-44, respectively, of copending Application No. 11/036,029 to Saadat et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are merely broader in scope than that of copending Application No. 11/036,029 as all essential limitations are similar.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-33, 36-38, 40-43 and 65-77 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0096502 to Khalili.

In regards to claims 31 and 65, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a substantially flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for

Art Unit: 3739

insertion within a body lumen (see paragraph 0078); at least two working lumens 330, 332 extending through the flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating element is *configured* to articulate from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b).

In regards to claims 32 and 66, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

In regards to claims 33, 41 and 70-71, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

In regards to claim 36, Khalili discloses a method for obtaining endoluminal access, further comprising injecting or withdrawing fluid through the working lumen (see paragraph 0068).

In regards to claims 37, Khalili discloses an apparatus for obtaining endoluminal access, wherein the apparatus has a delivery configuration in which the articulating element is aligned with or adjacent to the working axis of the elongate body, and a deployed configuration wherein the articulating element is articulated off-axis from the working axis of the elongate body (see Figs. 1a-d and paragraphs 0009-0016).

In regards to claims 38 and 40, Khalili discloses an apparatus for obtaining endoluminal access, wherein the distal opening is covered by the articulating element in the deliver configuration as the articulating element is capable multiple degrees of freedom, thus allowing manipulation of the element in and out of line with the working axis as desired (see Figs. 1a, 8 and paragraphs 0013, 0071).

In regards to claim 67, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

In regards to claims 68-69, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

In regards to claim 72, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

In regards to claim 73, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

In regards to claims 42-43 and 74-75, Khalili on discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

In regards to claim 76, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

In regards to claim 77, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5-9, 19, 23-24, 26-27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0096502 to Khalili in view of U.S. Patent No. 5,251,611 to Zehel et al.

In regards to claim 1, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for insertion within a body lumen (see paragraphs 0078); at least two working lumens 330, 332 extending through the flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating element is *configured* to articulate from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b). Khalili disclose that the elongated body the elongated body 4 may be rigid, flexible, or partially flexible depending on the particular application. For example, for laprascopic surgery, it may be desirable to have a rigid elongated body. For insertion into a patient's stomach, the distal section 6 of the elongated body may be rigid, and the proximal section 8 may be flexible so that it can be easily inserted down the esophagus (see paragraph 0048). However, Khalili is silent with respect to the elongate body comprising a plurality of links and at least one tensioning wire whereby the elongate body has a first, substantially flexible state and a second, substantially rigid state. Zehel et al. teach of an analogous apparatus wherein a preferred inner flexible conduit 10

Art Unit: 3739

consisting of a plurality of generally cylindrically shaped beads or segments 19 strung on flexible cables 20 passing slidably through the segments 19 by way of a channel 21 bored therein, as best seen in FIG. 3. Alternatively, the cables 20 may be slidably disposed within the segments 19 by means of loops, grooves, or any other means slidably retaining the cables 20 at their radial position with respect to the segment, whether the cable is relaxed or flexed (see Figs. 1-3 and Col. 6, Line 40- - Col. 7, Line 50). Furthermore, Zehel et al. teach that the device thus can be an add-on device for an existing endoscope or the stiffening feature may be included in the basic endoscope and one or more segmented concentric devices of the invention may be used around the endoscope (see Col. 10, Lines 20-37). It would have been obvious to one skilled in the art to at the time the invention was made to construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

In regards to claim 2, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

In regards to claim 5, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

In regards to claims 6-7, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

In regards to claims 8-9, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

In regards to claim 19, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

In regards to claim 23, Khalili discloses an apparatus for obtaining endoluminal access further comprising a housing configured to couple the articulating element to the elongate body and to facilitate articulation of the articulating element (see Figs. 13a-b and paragraph 0078).

In regards to claim 24, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

In regards to claims 26-27, Khalili discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

In regards to claim 29, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

In regards to claim 30, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

Response to Arguments

Applicant's arguments filed April 15, 2009 have been fully considered but they are not persuasive.

Applicant states that Khalili fails to disclose an articulating element that is pivotally connected to the elongate body by a linkage member that is pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body. Examiner disagrees. Khalili discloses that the device's distal end may comprise a plurality of leaflets. The device with its leaflets 302, 304, 306 in the closed position, as shown in FIG. 13A, allows easy insertion of the device into a patient's body. For deployment of the robotic arms, the leaflets 302, 303, 304 expands radially and exposes the robotic arms, as shown in FIG. 13B. In this variation, the each of the robotic arms 312, 314, 316 are attached to the distal ends of the leaflets 302, 204, 306 through a joint. A displacement interface 320 is provided at the midsection of each leaflet so that the leaflets may expand longitudinally. Motors or actuators may be

Art Unit: 3739

implemented inside the body of the device to control the angel of the leaflets as they are opened up. Each of the robotic arms 312, 314, 16 has an extension section 322 that may be extended or retracted to change the reach of the arm. In addition, each of the arms may rotate along the longitudinal axis along the length of the arm. Thus, as broadly as claimed, Khalili discloses at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs Figs. 13a-c and 0079-080). Furthermore, as seen in Figure 13b, a distal opening of one of the working lumens 330 is substantially uncovered, or exposed, as the articulating elements 302-304, 312-314 are moved to an off-axis position. The working lumen holds a camera for diagnostic purposes.

Furthermore, in response to applicant's argument that a distal opening is uncovered in an off-axis configuration, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). It is noted that, the words "configured to" in the claim may be properly interpreted as "capable of," and "capable of" does not require that reference actually

Art Unit: 3739

teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew J Kasztejna/
Examiner, Art Unit 3739

5/20/9